

Congress of the United States

Washington, DC 20515

April 25, 2017

The Honorable Gene L. Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, NW
Washington, D.C. 20548

Dear Comptroller General Dodaro:

We write today asking the Government Accountability Office (GAO) to investigate the food safety system and any remaining gaps in the oversight of imported seafood that are potentially dangerous to the public health of American citizens.

According to the National Marine Fisheries Service, in 2014 approximately 94% of the seafood consumed in the United States was imported, with imports increasing 3.2% from 2014 to 2015 for a total of over 2.6 million metric tons. Of this imported seafood, around half is farm-raised, and there remain serious problems with the food safety system for imported seafood. Because of the high rate of bacterial infection in farm-raised seafood, overseas producers often use antimicrobial agents – which in many instances are banned by the Food and Drug Administration for use in food-producing animals in the United States. The risk of residue is significant, and the health repercussions may be severe.

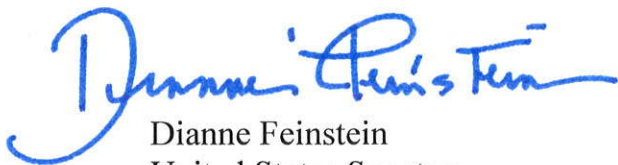
In this context, we ask that GAO follow up on and expand its previous work in the area of seafood safety, including the GAO report entitled *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources* (GAO-11-286), and address these additional questions:

1. What criteria does FDA use in developing import alerts for food products, including seafood, and once FDA has identified a problem, how long does it take, on average, for FDA to put the product, producer, country, or region on an import alert?
2. How does FDA make the determination to remove a company, country, or region from an import alert, and to what extent does FDA coordinate with other federal agencies, such as CBP, NMFS, and others, to help inform its decisions on adding or removing companies from import alerts?
3. Once an import alert is issued, how does FDA work with other federal agencies, such as CBP and NMFS, to ensure that food is not rerouted (transshipped) to avoid these alerts (and import duties)?

4. How does FDA measure the effectiveness of its import alerts, and to what extent has it assessed the results?
5. To what extent do other mechanisms, such as NMFS's fee-for-service inspection system and FDA's bilateral and multilateral food safety-related arrangements with other countries, help ensure the safety of imported food, including seafood?
6. What criteria does FDA use to determine risk for imported seafood, and to what extent do these criteria ensure comparable safety for imported and domestic food?
7. How many warning letters, if any, has FDA issued to foreign seafood facilities since 2011, and how long has it taken FDA, on average, to close out such warning letters?
8. How many regulatory actions (e.g., import refusals, seizures, injunctions, administrative detentions), if any, has FDA issued to foreign seafood facilities since 2011?

Thank you for your attention to our request. If you have any questions, please do not hesitate to contact us, or have your staff contact Joseph Petrzeka in Senator Feinstein's office at 202-224-2004.

Sincerely,



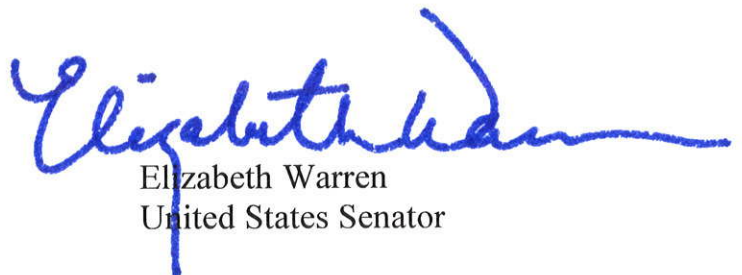
Dianne Feinstein
United States Senator



Patty Murray
United States Senator



Richard Blumenthal
United States Senator



Elizabeth Warren
United States Senator



Rosa L. DeLauro
Member of Congress

Attachment 1: Background on Imported Seafood Safety System

The Food and Drug Administration (FDA), under the U.S. Department of Health and Human Services, along with the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service, are responsible for overseeing the safety of most imported food. The National Marine Fisheries Service (NMFS), under the U.S. Department of Commerce, provides, among other things, fee-for-service inspections of seafood for industry.

The FDA is responsible for overseeing the safety of most imported food, with the exception of meat, poultry, catfish and liquid egg products, which are overseen by the U.S. Department of Agriculture's Food Safety and Inspection Service. Past GAO work has identified gaps in FDA's oversight of imported food, potentially leaving the U.S. food supply vulnerable to accidental or intentional contamination.¹ The National Marine Fisheries Service (NMFS), under the U.S. Department of Commerce, provides, among other things, fee-for-service inspections of seafood for industry. NMFS reported that in 2014, approximately 94 percent of the seafood consumed in the United States was imported, for a total of nearly 3 million metric tons. Of this imported seafood, about half is farm-raised; GAO and others have identified serious problems with the safety of imported seafood.²

Among the measures FDA uses to prevent unsafe food from entering the U.S. market are the issuance of import alerts, inspections of foreign establishments, and testing once seafood arrives in the U.S. To avoid import duties or regulatory controls, such as FDA's import alerts, some foreign producers may attempt to ship products, including seafood, to the United States through a third country, a practice known as transshipment.

According to GAO, FDA inspected just 1.5 percent of Chinese seafood processing facilities from 2005 to 2011; for fiscal years 2006 through 2009, FDA missed its assignment plan goal for collecting import samples by about 30 percent. In fiscal year 2009, FDA tested about 0.1 percent of all imported seafood products for drug residues.³ The Food Safety Modernization Act (P.L. 111-353) mandated increased inspections of foreign food processing facilities, but the FDA has not kept pace with statutory requirements, and the agency has not completed an analysis to determine the number of

¹*Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (GAO-09-873) Washington, D.C.: Sept. 15, 2009 and *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources* (GAO-11-286). Washington, D.C.: Apr. 14, 2011.

²GAO-11-286 and Gould L, Kline J, Monahan C, et al. "Outbreaks of Disease Associated with Food Imported into the United States, 1996–2014". *Emerging Infectious Diseases*. 2017;23(3):525-528. doi:10.3201/eid2303.161462.

³GAO-11-286.

inspections it deems sufficient to ensure comparable safety for imported and domestic food.⁴

Import alerts inform FDA field staff that the agency believes it has enough evidence or other information to refuse admission of future shipments of an imported article. An alert may be issued for a product from a manufacturer, shipper, grower, geographical area, or country. If the problem or condition exists on a wide scale, federal inspectors would be instructed to detain all products of a certain kind coming from the importing country. For its part, Customs and Border Protection (CBP) under the U.S. Department of Homeland Security, reviews import documentation to detect schemes to avoid paying the appropriate customs duties as seafood products enter the country. In 2009, GAO reported that CBP had determined that Chinese shrimp was being transshipped to the United States through Malaysia.⁵ Using this this illegal practice, importers of Chinese shrimp were able to circumvent both the 2005 anti-dumping duty and FDA's 2007 import alert on five Chinese-farmed seafood products, including shrimp. CBP tested shipments of suspected Chinese shrimp illegally transshipped through Malaysia for the presence of unapproved drugs and found contaminated shrimp.

In addition to import alerts, FDA also has various bilateral and multilateral food safety-related arrangements and agreements with numerous countries to ensure the safety of imported food. The two key types of agreements are (1) cooperative arrangements, which describe the willingness and good-faith intentions of FDA and its counterpart(s) to engage in cooperative activities, and (2) confidentiality agreements, which set up the legal framework for FDA to share certain kinds of nonpublic information with counterparts in other countries and international organizations as part of cooperative law enforcement or regulatory activities.

⁴ GAO, *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, (GAO-15-183). Washington, D.C.: Jan. 30, 2015 and GAO, *Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible* (GAO-16-399) Washington, D.C.: May 26, 2016.

⁵ *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention* (GAO-190258), Washington, D.C.: Feb. 19, 2009.